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Professional Standard of the People's Republic of China

YY/T 1794-2021

General technical requirements for dental collagen membrane

口腔胶原膜通用技术要求

(English Translation)

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General technical requirements for dental collagen membrane

1 Scope

This standard specifies the terms and definitions, classification, requirements and test methods for dental collagen membrane.

This standard is applicable to the membrane materials with collagen as the main component for repairing soft and hard oral tissue defects caused by various reasons, which plays a role of guiding, isolating, repairing, fixing, reducing tension and replacing.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 528-2009	*Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*
GB/T 1040.3-2006	*Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets*
GB 5009.6-2016	*National food safety standard — Determination of fat in foods*
GB/T 6682-2008	*Water for analytical laboratory use — Specification and test methods*
GB/ T 14233.1-2008	*Test methods for infusion, transfusion, injection equipments for medical use — Part 1: Chemical analysis methods*
GB/T 14233.2-2005	*Test methods for infusion, transfusion, injection equipment for medical use — Part 2: Biological test methods*
GB/T 16886.1	*Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*
GB/T 16886.3	*Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
GB/T 16886.4	*Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*
GB/T 16886.5	*Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*
GB/T 16886.6	*Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*
GB/T 16886.7	*Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*
GB/T 16886.10	*Biological evaluation of medical devices — Part 10: Tests for*

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	irritation and skin sensitization
GB/T 16886.11	*Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*
GB/T 16886.12	*Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*
GB/T 16886.20	*Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices*
YY/T 0127.2	*Biological evaluation of medical devices used in dentistry — Part 2: Test method — Acute systemic toxicity: intravenous path*
YY/T 0127.4	*Biological evaluation of medical devices used in dentistry — Part 2: Test method — Bone implant test*
YY/T 0127.8	*Biological evaluation of dental materials — Part 2: Biological evaluation test method of dental materials — Subcutancous implant test*
YY/T 0127.10	*Biological evaluation of medical devices used in dentistry — Part 2: Test method — Salmonella typhimurium reverse mutation assay (Ames mutagenicity test)*
YY/T 0268	*Dentistry — Biological evaluation of medical devices used in dentistry — Part 1: Evaluation and test*
YY/T 0606.25-2014	*Tissue engineered medical product — Part 25: Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives: Fluorescence method*
YY 0954-2015	*Nonactive surgical implants — Type I collagen implants — Specific requirements*
YY/T 1511-2017	Collagen sponge

Pharmacopoeia of the People's Republic of China (2020)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
dental collagen membrane
dental membrane material with collagen as the main component, generally including purified collagen membrane, recombinant collagen membrane and acellular matrix membrane (purified collagen membrane: membranous product prepared by physical or chemical crosslinking of collagen extracted from animal tissues; recombinant collagen membrane: membranous product prepared by physical or chemical crosslinking of collagen prepared by genetic engineering technology; acellular matrix membrane: membrane with the extracellular matrix as the main component that is obtained by removing the cellular components of tissues/organs by chemical and/or physical methods, while retaining its organizational structure)

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3.2
patch utilizing animal tissues and their derivatives animal derived materials
materials containing animal derived materials (animal tissues and their derivatives), all or part of which are made of animal tissues, and materials made of animal tissue derivatives or substances naturally obtained from animal bodies through special processing, which can be used for filling, repairing, barrier and anti-adhesion of defective tissues

3.3
type I collagen
collagen composed of two α_1 peptide chains and one α_2 peptide chain, whose structure has triple helix characteristics, in which, arranged into bundles regularly, five collagen molecules aggregate to form collagen fibrils, and multiple collagen fibrils are connected end-to-end and head-to-tail according to rules to form type I collagen fibers with different thicknesses

3.4
additives
natural or synthetic substances which are added in medical devices during the production, processing or storage, and expected to achieve a special purpose in the final products, e.g., crosslinking agents, modifiers, protectants, antibacterial agents, inorganic minerals, etc.

4 Classification

Dental collagen membrane materials may be classified as follows: crosslinked membrane and non-crosslinked membrane according to whether they are crosslinked or not; allogeneic and xenogeneic according to the source; dermal matrix membrane, pericardium and small intestinal submucosa membrane according to the origin; acellular matrix membrane, purified collagen membrane and recombinant collagen membrane according to the process; guided tissue regeneration (GTR) membrane, guided bone tissue regeneration membrane, gingival mucosa and other soft tissue repair regeneration membranes according to the intended use.

5 Requirements

5.1 Physical and mechanical properties

5.1.1 Appearance

It shall meet the requirements of the manufacturer.

5.1.2 Dimensions

It shall meet the requirements of the manufacturer.

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